IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DEPOSITION TESTIMONY

I. INTRODUCTION AND SUMMARY OF THE ACTAVIS DEFENDANTS' OPPOSING BRIEF

Plaintiffs, via a Rule 37 Motion to Compel, seek an order requiring the Actavis Defendants to answer deposition questions pertaining to "the production, manufacturing processes, current good manufacturing practices ("GMPs"), quality control, and quality assurance of *all pharmaceuticals* produced at the Actavis Totowa facilities during the relevant time period." (Doc. 301, at 1, emphasis added.) This broad request is untethered to any specific question or enumerated questions as contemplated under Rule 37(3)(B). Plaintiffs' motion – in reality – is a motion for reconsideration of PTO Nos. 27 and 37 that should be denied.

PTO Nos. 27 and 37 compel denial of Plaintiffs' motion. The issue presented was fully and directly briefed and decided months ago in PTO Nos. 27 and 37, which govern *all* discovery in this MDL – not just document production. To date, Defendants' objections and instructions to witnesses at deposition have been fully consistent with those Orders, allowing for testimony as to: 1) Digitek®; and 2) general practices and procedures at Actavis Totowa; but 3) disallowing testimony in response to inquiry into facts and circumstances specific to the manufacture and production of non-Digitek® products. Plaintiffs' motion attempts to subvert the orders. Not

surprisingly, they do not move the Court to reconsider PTO Nos. 27 and 37 in any way. That is because they are well outside of the twenty-eight day timeframe for doing so under Rule 59(e). Nor could they meet the stringent requirements of Rule 59(e) as applied to reconsideration motions.

Substantively, Plaintiffs provide no justification for the order requested. Defendants have consistently allowed witnesses to answer questions that fall within the parameters of PTO Nos. 27 and 37. In short, Plaintiffs are already getting the deposition answers they seek via their motion when their questions are properly phrased. (*See, e.g.*, Exhs. B and C.)

PTO Nos. 27 and 37 apply to the issue before the Court, are not remotely undermined by the deposition testimony of Richard Dowling, and are outcome-determinative. Plaintiffs' Motion to Compel should therefore be denied.

II. THE GENESIS OF PTO NO. 27 AND ITS CONTROLLING PROVISIONS

Well over a year ago, the parties negotiated the terms of, and entered into, Pretrial Order No. 12 (Stipulated Protective Order) (Doc. 71). That order: 1) recognizes that Digitek® is the only product mentioned in Plaintiffs' Master Complaint and is, therefore, the only relevant product in this litigation; and 2) protects from discovery *all* information regarding non-Digitek® products, with an exception for certain manufacturing information about non-Digitek® products that is "reasonably related" to Digitek® manufacturing information. (*Id.*)

Four months after the parties negotiated the terms of the Stipulated Protective Order, Plaintiffs moved the Court "to expand the scope of discovery from Digitek® only, to include all manufacturing processes of the Actavis Totowa Little Falls, New Jersey facility for all product lines." (Doc. 150, at 2, citing Doc. 144, at 6.) That motion was in no way limited to document production. It sought an expansion of the scope of *all* discovery based on Plaintiffs' position that: 1) there was a commingling of product lines within Actavis Totowa; and 2) equipment and

personnel were used interchangeably to manufacture all products. (*Id.*) Thus, Plaintiffs argued that there was a likelihood that any incidents that occurred during the production of one product would be similar if not identical to an incident involving Digitek® production. (*Id.* at 5, citing Doc. 144, at 7-8.) Plaintiffs asserted that the manufacturing processes of all products were "reasonably related" and that discovery concerning those manufacturing processes should be allowable under the relevancy provisions of Federal Rule of Civil Procedure 26. (*Id.* at 8, citing Doc. 147, at 3-13.) Defendants responded, and the issue of broadening the scope of all discovery on relevancy grounds was fully briefed.

In PTO No. 27, this Court fully analyzed the facts and legal argument under Federal Rule of Civil Procedure 26 and rejected Plaintiffs' "relevancy" argument: "Plaintiffs contention that an incident involving one product 'would be similar or even identical' to an incident involving Digitek® is too speculative to justify the enormous and expensive expansion of discovery they seek." (Doc. 150, at 15.) This finding included a limited exception to "include records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek®." (*Id.*) The Court based this exception on a specific FDA observation tying an issue of cleaning validation studies directly to Actavis' manufacture and production of "digoxin tablets, USP, 0.25 mg." (*Id.* at 5.) Nothing in the Court's order limits its finding only to document production. PTO No. 37 affirmed PTO No. 27.

To enforce PTO Nos. 27 and 37, Defendants have been instructing witnesses under Rule 30(c)(2) not to answer deposition questions seeking information about specific non-Digitek® products. Plaintiffs claim that Defendants incorrectly rely on the Protective Order to justify this instruction. (Doc. No. 301, at 9.) The Protective Order, however, makes clear that it applies not

only to produced documents, but also to "all other information produced or disclosed during this proceeding . . . whether revealed in a document, deposition, other testimony . . . or otherwise." (PTO No. 12, § I(B).) Indeed, it would be illogical to allow Defendants to keep non-Digitek® information from Plaintiffs by redacting it from documents, but allow Plaintiffs to get the exact same information through deposition testimony. Nor is the Protective Order the sole basis for Defendants' instructions; rather, the instructions flow from reading the Protective Order (where Plaintiffs explicitly agreed they were not entitled to product-specific information about drugs other than Digitek®), together with PTO Nos. 27 and 37, where this Court made clear that: 1) "[t]he Master Complaint's claims relate only to the medication Digitek®"; and 2) it was granting only a "modest expansion" to the scope of discovery about products other than Digitek® in this litigation. (Doc. 150, at 12, 15.)

Simply put, Plaintiffs disregard the reality that this Court conducted its analysis regarding the appropriate scope of discovery in this litigation entirely *from* PTO No. 12. The holding of PTO No. 27 (and thus PTO No. 37) reflects the Court granting an expansion of the agreed-upon scope of relevancy defined in PTO No. 12, because the Court concluded that the narrow range of additional information Plaintiffs sought was "reasonably related to Digitek® manufacturing as that phrase is used in Pretrial Order #12, Section II.F.4." (Doc. 150, at 17.)

In November 2009, Plaintiffs again attempted to expand the scope of discovery – this time in a different jurisdiction. They were unsuccessful. Expressly relying on PTO No. 27, the Honorable Sandra Mazer Moss, in *In re Digitek®*, Consolidated Docket No. March Term 2009, No. 5166, denied, with the same limited exception this Court allowed, Plaintiffs' Motion to Compel the Deposition Testimony of Actavis' Employees Regarding Quality Assurance and Quality Compliance Issues of Products other than Digitek®. (*See* Exh. A.)

Now, for the third time, Plaintiffs seek a ruling that would broaden the scope of discovery to include "the production, manufacturing processes, current GMPs, quality control, and quality assurance of *all pharmaceuticals* produced at the Actavis Totowa facilities during the relevant time period" on relevancy grounds. (Doc. 301, at 1, emphasis added.) They seek such a ruling under the guise of a motion to compel when clearly what they seek is an overhaul of PTO Nos. 27 and 37 to fit their current and ever-changing theory of liability in this litigation.

III. LEGAL ARGUMENT

The provisions of PTO No. 12 were acceptable to Plaintiffs when their theory of liability was the alleged manufacture and distribution of double-thick Digitek® tablets. As it became clear that no such tablets ever made it into the stream of commerce, Plaintiffs' new theory became defective tablets of normal size, containing too much or too little digoxin. That theory would, according to Plaintiffs, allow them to probe into the manufacturing process for not only Digitek®, but all product lines. Not so under PTO Nos. 27 and 37. Now, almost two years from the Digitek® recall, Plaintiffs still have no *direct* evidence of defective Digitek® ever having been given to or consumed by any consumer, whether the tablets were oversized or not. Plaintiffs thus consistently want to expand the scope of discovery with the hope of finding enough non-Digitek®, general manufacturing or quality problems to fuel the potential for proving product defect *indirectly*. But the only way they can try that "go-fish" approach is through an overhaul of the provisions of PTO Nos. 27 and 37. Their Rule 37 motion to compel does not, and cannot, accomplish that task. It lacks merit at every level and should be denied.

A. PTO Nos. 27 and 37 Require Denial of Plaintiffs' Motion.

Plaintiffs' Rule 37 Motion to Compel seeks an order compelling deposition testimony pertaining to subject matter grossly beyond the scope of discovery in this litigation as defined under PTO Nos. 12, 27, and 37. They list no specific questions they would like to have

answered, as contemplated under Rule 37(3)(B), but instead seek an order that would apply, both retroactively and prospectively and in the abstract, to all witnesses; an order that would substantially revise PTO Nos. 27 and 37. Yet, plaintiffs do not move for reconsideration of those orders. This backdoor approach via Rule 37 is an apparent attempt to get out from under the provisions of Federal Rule of Civil Procedure 59(e).

The Fourth Circuit entertains motions for reconsideration under Rule 59(e) to: 1) accommodate an intervening change in controlling law; 2) account for new evidence; or 3) correct a clear error of law or prevent manifest injustice. *Hutchinson v. Staton*, 994 F.3d 1076, 1081 (4th Cir. 1993); *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998); *Hill v. Braxton*, 277 F.3d 701, 708 (4th Cir. 2002). As a general rule, "reconsideration of a judgment after its entry is an extraordinary remedy which should be used sparingly." *Pac. Ins. Co.*, 148 F.3d at 403 (quoting 11 Wright et al., *Federal Practice and Procedure* § 2810.1, at 124 (2d ed. 1995). Further, "Rule 59(e) motions may not be used . . . to raise arguments which could have been raised prior to the issuance of the judgment, nor may they be used to argue the case under a novel legal theory that the party had the ability to address in the first instance." *Id.* "Mere disagreement [with a court's ruling] does not support a Rule 59(e) motion." *U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 290 (4th Cir. 2002). A motion for reconsideration filed under Rule 59(e) must be filed within 28 days after the entry of judgment, and the rule does not provide a mechanism for extending the prescribed filing deadline. *Panhorst v. U.S.*, 241 F.3d 367, 370 (4th Cir. 2001) ("the Federal Rules clearly prescribe that a motion under Rule 59(e) must be filed within [twenty-eight] days after the entry of the judgment, and the Rules just as clearly provide the district court with no authority to extend the filing period").

Here, Plaintiffs are well outside the prescribed 28-day filing deadline under Rule 59(e); PTO #27 issued on July 1, 2009, and was affirmed on August 10, 2009. And Plaintiffs have not remotely met their Rule 59(e) burden substantively.

Moreover, Plaintiffs provide no justification for the order they request. They can indeed obtain the type of non-Digitek®-specific testimony they seek within the confines of PTO Nos. 27 and 37. This type of testimony has *not* been precluded, as Plaintiffs suggest. Actavis has always allowed general questioning about manufacturing processes, GMPs, quality control, and quality assurance at the Actavis Totowa facility, and with respect to Digitek®. The only testimony it has precluded are responses to questions regarding those practices with reference to specific products *other than* Digitek®, consistent with PTO Nos. 27 and 37.

Plaintiffs' own deposition testimony examples establish this point. The first example (Doc. 301, at 2) shows that Actavis objected to a deposition question about the connection of GMP issues to the "shut down of production of *all* products" at Actavis Totowa. (*Id*., emphasis supplied.) The witness was instructed to answer, but "only with respect to Digitek®." (*Id*.) Plaintiffs' second example (*id*. at 3) likewise shows an objection to a deposition question inquiring about blend uniformity problems among "any product that was being produced at the Little Falls plant." (*Id*.) Following an objection, the witness was instructed to answer but "only with respect to Digitek®." (*Id*.)

If, as Plaintiffs argue, the manufacturing, production, GMPs, quality control and quality assurance procedures and systems were the same for every product manufactured at Actavis Totowa (Doc. 301, at 3-6, 8-11), then Plaintiffs may ask general questions about those procedures and systems without referring to non-Digitek® products. Plaintiffs have been permitted to ask these questions. This is best illustrated in the deposition transcript of Phyllis

Lambridis, former Vice President of Quality and Compliance at Actavis Totowa. (Excerpts from the Phyllis Lambridis deposition transcript ("Lambridis Dep."), taken January 18, 2010, is attached as Exh. B.)

At the Lambridis deposition, the main examiner for the Plaintiffs was Edward Blizzard. He got it right in asking general questions about procedures and systems, untethered to a non-Digitek® product. (*See* Exh. B, providing highlighted examples of Mr. Blizzard's questioning.) At no point during his wide-ranging inquiry was the deponent instructed by defense counsel not to answer a question about a non-Digitek® product. It was only when other questioners took over and made specific inquiry into non-Digitek® products that instructions were given to the witness, and those instructions clearly permitted the witness to answer all general and Digitek®-specific questions. *E.g.*:

> Q. And I'll point out that you can answer with respect to Digitek® or any general GMP violations. It can be general issues or Digitek®. It doesn't have to be just Digitek®.
>
> MR. DEAN: At a general level, I'm fine. But if you're asking her for specific comments about non-Digitek® drugs, I think that is beyond the scope of what's in PTO-12 and 27. If you're at a general level, I'm okay with it. But I think your last question could lead her to go into specifics. And I'm just instructing her, as to specifics, to limit it to Digitek®.

(Exh. B at 294:19-25; 295:1-8.)

> MR. DEAN: Let me just instruct the witness she can answer questions at a general level about this document; but, again, given PTO 12 and 27, I don't want her to get into specific discussions of products other than Digitek®. But she can answer your questions at a general level regarding this document.

(*Id*. at 299:3-11.)

> MR. DEAN: Let me object and reiterate the objection I gave before and instruct her not to answer about details of other non-Digitek® drugs. She can certainly answer about Digitek®, and she can answer at a general level.

(*Id*. at 305:17-23.)

The full range of general inquiry Defendants have allowed Plaintiffs to pursue is consistent with objections made, and the testimony allowed, by Actavis' counsel during other depositions. Excerpts from the deposition testimony of four additional witnesses involved in some aspect of Quality Systems operations at Actavis (Mr. Bitler, Mr. Roychowdhury, Mr. Talbot, and Mr. Galea) establish this point.[1] (*See* Exh. C, Tabs 1-4, respectively, providing highlighted excerpts.) In short, if Plaintiffs' deposition questions are phrased properly under PTO Nos. 27 and 37, they can get the information they seek by this motion.

B. PTO Nos. 27 and 37 Are Not Undermined by the Deposition Testimony of Richard Dowling.

Plaintiffs make the outrageous allegation that the affidavit testimony of Richard Dowling is false – that he lied in a sworn statement to this Court – and that, because the Court placed significant weight on that testimony in issuing PTO Nos. 27 and 37, the pretrial orders should not stand. (Doc. 301, at 12-13.) This is flat-out incorrect.

Mr. Dowling's affidavit testimony speaks to the unique manufacturing *system* used to produce Digitek®. Plaintiffs, in turn, attempt to isolate the component parts of that system, and then use evidence relating only to some of those specific component parts to undermine: 1) any unique quality to the Digitek® manufacturing process; and 2) Mr. Dowling's credibility. That strategy is obvious and fails to reach its goal. It is best exposed by way of example.

[1] While it is not always immediately discernible whether a deposition question is seeking general information or non-Digitek® product-specific information, Defendants have tried to achieve as much consistency as possible in allowing answers to general questions.

Plaintiffs claim that paragraph 14 of the Richard Dowling affidavit is false when compared to his deposition testimony. But their argument omits significant testimony in both Mr. Dowling's affidavit and deposition. Paragraph 14 is just one of several paragraphs relevant here. It provides:

> Digitek® is produced using what effectively is a custom, Digitek®-only tablet press. The base model and make of the tablet press used to manufacture all of the recalled Digitek® is a 45 station Stokes BB2 tablet press. Each time Digitek® is manufactured, the Stokes BB2 45 station press is customized using very unique "tooling" – punches and dies – designed solely and exclusively for the purpose of manufacturing Digitek® on that tablet press.

(Doc. 146, pp. 30-37, ¶ 14.)

Paragraph 15 makes clear that "punches" includes "an *upper punch* and a lower punch." (*Id*., ¶ 15, emphasis added.) Thus, the "tooling" referenced in paragraph 14 consists of a complete set of *three* pieces – an upper punch, a lower punch, and a die. (*Id*., ¶¶ 14, 15) Paragraph 17 makes clear that the upper punch contains marking on the tip which results in each individual Digitek® tablet being embossed with an appropriate label corresponding to its product identification number. (*Id*., pp. 30-37, ¶ 17). Paragraphs 18, 19, and 20 provide further testimony about the handling and storage of the "unique tooling" that is first defined in paragraph 14 and further discussed in paragraphs 15, 17, 18, 19 and 20. Plaintiffs simply ignore the fact that the term unique "tooling" is expressly defined in Mr. Dowling's affidavit to include the upper punch, the lower punch, and the die.

The e-mail Plaintiffs rely on for their claimed inconsistency (Doc. 301, at 11-12) only refers to the lower punch and the die – two component parts – and makes no reference to the upper punch or the system into which these components are integrated to produce Digitek®. When Mr. Dowling stated that the lower punch and the die were potentially used to make

products other than Digitek® (in the e-mail and during his deposition) he was not in any way contradicting his affidavit testimony that each tablet press used to make Digitek® was unique because of the unique "tooling" used to set up the press before manufacturing.

During his deposition, Mr. Dowling was repeatedly forced to make this clarifying point. Plaintiffs' counsel initially started by blatantly ignoring the distinction between the Digitek® manufacturing system as a whole, and two stand-alone component parts, asking: "[T]he punches and dies were not reserved solely to use for Digoxin were they?" (Excerpts from the deposition transcript of Richard Dowling ("Dowling Dep."), taken December 16, 2009, at 199:9-11, are attached as Exh. D.) Mr. Dowling clarified this issue in his response – "the lowers and dies were used interchangeably" (*id*. at 199:12-13).

Plaintiffs' counsel tried to badger Mr. Dowling again into saying his affidavit testimony was incorrect.[2] "[D]idn't you just testify that as of December 18, 2007, that you used the punches and dies interchangeably to make products other than Digitek?" (*id*. at 201:12-15). When Mr. Dowling declined to agree that his affidavit testimony was incorrect, and again affirmed that the company used "unique tooling" on the Digitek® tablet presses, Plaintiffs' counsel simply continued: "[Y]ou used the punches and dies as of December 18, 2007 to make tablets other than Digitek®; isn't that right?" (*id*. at 202:3-5). And again, Mr. Dowling clarified that this statement only applied to the lower punches and dies. (*Id*. at 202:8-9).

[2] Plaintiffs omitted pages 201-209 of Mr. Dowling's deposition transcript when they filed their Motion. These pages contain testimony that show the over-reaching nature of Plaintiffs' deposition questions.

Undeterred, Plaintiffs' counsel made another effort:

> Let's start over again. Let's make sure we understand each other. Let's go to the e-mail of December 18, 2007, and we'll work our way back through that one more time. As of December 18, 2007, the punches and dies that were utilized for the making of Digitek® were utilized in making multiple products; is that not correct?

(*Id*. at 204:14-21.) Mr. Dowling yet again clarified that "the lower punches and dies were used for other products, yes." (*Id*. at 205:1-3.)

Remarkably, Plaintiffs' counsel was not finished: "That's what you said on December 18, 2007, in your e-mail to Mr. Patel. Now, the fact is that you wrote Paragraph 14 telling the Court under oath that the punch and the die was unique and used solely to produce Digitek." (*Id*. at 206:13-18.) Mr. Dowling then restated his definition of unique tooling:

> Again, my description of unique tooling here [in Paragraph 14 of his Affidavit] is tooling that is designated in the batch record for Digitek, either strength, with a numbered designation of a container which contains that tooling for both the upper punch, the lower punch, and the dies, and instructs the operator to pull that tooling to set that press for Digitek.

(*Id*. at 207:18-208:4.)

In short, Plaintiffs' "Dowling strategy" does not meet its intended goal. There is no basis for the Court to question the reliability of Mr. Dowling's affidavit testimony or to revisit PTO Nos. 27 and 37.

IV. CONCLUSION

Plaintiffs' Motion for Reconsideration of PTO Nos. 27 and 37, submitted as a Rule 37 Motion to Compel, should be denied as untimely and for lack of merit. It is an apparent attempt to subvert PTO Nos. 27 and 37. Those orders, however, squarely apply to the issue presented, and under them, Plaintiffs' motion should fail.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2010, a copy of the foregoing **Defendants' Brief in Opposition to Plaintiffs' Motion to Compel Deposition Testimony** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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